902 KAR 20:420. Pain management facilities.

RELATES TO: KRS 198B.260, 216B.010-216B.131, 216B.990, 218A.175, 311, 314, 29 C.F.R. 1910.1030(d)(2)(vii), 21 U.S.C. 801 - 971

STATUTORY AUTHORITY: KRS 216B.042, 216B.105, 218A.175

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. KRS 216B.105 authorizes the cabinet to promulgate administrative regulations to deny, revoke, modify, or suspend a license issued by the cabinet, if it finds that there has been a substantial failure to comply with the provisions of KRS Chapter 216B or this administrative regulation. KRS 218A.175 imposes a physician-ownership or investment requirement on all pain management facilities except for those health facilities operating as a pain management facility on April 24, 2012, unless there is an administrative sanction or criminal conviction relating to controlled substances imposed on the facility or any person employed by the facility for an act or omission done within the scope of the facility's license or the person's employment. This administrative regulation establishes the minimum licensure requirements for the operation of a pain management facility that is exempt from the physician-ownership requirement of KRS 218A.175.

- Section 1. Definitions. (1) "Adverse action" means action taken by the Cabinet for Health and Family Services, Office of Inspector General, to deny, suspend, or revoke a pain management facility's license to operate.
- (2) "License" means an authorization issued by the cabinet for the purpose of operating a pain management facility.
- (3) "Licensee" means the owner, individual, agency, partnership, or corporation, in which the ultimate responsibility and authority for the conduct of the pain management facility, or a satellite facility, is vested.
- (4) "National and State Background Check Program" means an initiative implemented by the cabinet pursuant to 906 KAR 1:190 for the performance of:
 - (a) Registry checks; and
- (b) Fingerprint-supported criminal background checks performed by the Department of Kentucky State Police and the Federal Bureau of Investigation.
 - (5) "Pain management facility" or "facility" is defined by KRS 218A.175(1)
- (6) "Satellite facility" means a pain management facility permitted by KRS 218A.175(2)(b) to open and operate under the license of a parent pain management facility that:
- (a) Is licensed under this administrative regulation pursuant to the physician-ownership exemption of KRS 218A.175(2)(a); and
 - (b) Does not have a pending adverse action.
- (7) "Unencumbered license" means a license that has not been restricted by the state professional licensing board due to an administrative sanction or criminal conviction relating to a controlled substance.
- Section 2. Satellite Facilities. A satellite facility shall comply with the requirements established by this administrative regulation for parent pain management facilities, including background checks, administration, staffing, equipment, and physical environment.
 - Section 3. Ownership. (1) A facility licensed pursuant to this administrative regulation shall

be immediately disqualified from the physician-ownership exemption of KRS 218A.175, and the cabinet shall revoke the facility's license pursuant to Section 11(3) of this administrative regulation if:

- (a) An administrative sanction or criminal conviction relating to a controlled substance is imposed on the parent or satellite facility or any person contracted or employed by the parent or satellite facility for an act or omission done within the scope of the facility's licensure or the person's employment; or
- (b) A change of ownership occurs, except for a transfer of whole or partial ownership as permitted by KRS 218A.175(2)(b).
- (2)(a) A change of ownership shall be deemed to occur if any ownership interest, or capital stock or voting rights of a corporation is purchased, leased, or otherwise acquired by one (1) person from another for an existing facility licensed pursuant to this administrative regulation.
- (b) The pain management facility's license shall not be transferred to a new owner, except for a transfer of whole or partial ownership interest in the facility as permitted by KRS 218A.175(2)(b).
- Section 4. Background Checks and Prohibition Against Employment. (1)(a) All owners, operators, and employees, including contract employees of a pain management facility, shall submit to a fingerprint-supported national and state criminal background check.
- (b) A facility may use Kentucky's National and State Background Check Program established by 906 KAR 1:190 to satisfy the criminal background check requirement of paragraph (a) of this subsection.
- (2) A facility shall not be licensed if owned in part by, contracts with, or employs a physician or prescribing practitioner:
 - (a) Whose Drug Enforcement Administration number has ever been revoked;
- (b) Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction;
 - (c) Who has had any disciplinary limitation placed on his or her license by:
 - 1. The Kentucky Board of Medical Licensure;
 - 2. The Kentucky Board of Nursing;
 - 3. The Kentucky Board of Dentistry;
 - 4. The Kentucky Board of Optometric Examiners;
 - 5. The State Board of Podiatry:
- 6. Any other board that licenses or regulates a person who is entitled to prescribe or dispense controlled substances to humans; or
- 7. A licensing board of another state if the disciplinary action resulted from illegal or improper prescribing or dispensing of controlled substances; or
- (d) Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed as Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V in this state or the United States.
- (3) In addition to physicians and prescribing practitioners, a facility shall not employ any individual directly, or by contract, who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, a drug-related offense as described in subsection (2)(d) of this section.

Section 5. Licensure Application, Fee, and Renewal. (1) A licensee which elects to open and operate no more than two (2) additional satellite facilities shall:

(a) As a condition precedent to adding a satellite facility to the parent pain management fa-

cility's license, ensure that the satellite facility is in compliance with this administrative regulation and KRS 218A.175, which may be determined through an on-site inspection of the satellite facility; and

- (b) Submit a completed Application for License to Operate a Pain Management Facility prior to opening the satellite facility accompanied by a fee of \$2,000 per each satellite facility.
 - (2) A license shall:
 - (a) Expire one (1) year from the date of issuance; and
 - (b) Be renewed if the licensee:
- 1. Submits a completed Application for License to Operate a Pain Management Facility accompanied by an annual re-licensure fee of \$2,000, plus a fee of \$2,000 per satellite facility; and
 - 2. Has no pending adverse action.
- (3) A pain management facility that does not have a pending adverse action but has failed to renew its license on or before the expiration date shall cease operating the facility unless:
 - (a) The items required under subsection (2)(b) of this section have been submitted; and
- (b) The Office of Inspector General has provided the facility with a notice granting temporary authority to operate pending completion of the renewal process.

Section 6. Facility Patients. To determine if the majority of patients of the practitioners at the facility are provided treatment for pain that includes the use of controlled substances, the Office of Inspector General:

- (1) Shall have access to the facility pursuant to KRS 216B.042, including the facility's patient records:
- (2) Shall calculate the majority of patients based upon the number of unduplicated patients treated in a one (1) month time period; and
- (3) May use data from the Kentucky All Schedule Prescription Electronic Reporting (KASPER) Program to determine if the majority of the patients of the facility's practitioners are prescribed controlled substances.

Section 7. Administration Requirements for Parent and Satellite Pain Management Facilities. (1) A facility shall be located in a fixed site.

- (2) Each facility shall post the license conspicuously in a public area of the facility.
- (3) Licensee.
- (a) The licensee shall be legally responsible for:
- 1. All activities within the facility, including the actions of the physicians and prescribing practitioners; and
- 2. Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the facility, including the Drug Abuse Prevention and Control Act (21 U.S.C. 801 to 971 et. seq.) and KRS Chapter 218A, 902 KAR Chapter 20, and 902 KAR Chapter 55.
 - (b) The licensee shall establish lines of authority and designate an administrator who:
 - 1. May serve in a dual role as the facility's medical director; and
 - 2. Shall be principally responsible for the daily operation of the facility.
- (4) Policies. The facility shall establish and follow written administrative policies covering all aspects of operation, including:
- (a) A description of organizational structure, staffing, and allocation of responsibility and accountability;
 - (b) A description of linkages with inpatient facilities and other providers;
 - (c) Policies and procedures for the guidance and control of personnel performances;
 - (d) A written program narrative describing in detail each service offered, methods and proto-

cols for service delivery, qualifications of personnel involved in the delivery of the services, and goals of each service;

- (e) A description of the administrative and patient care records and reports;
- (f) Procedures to be followed if the facility performs any functions related to the storage, handling, and administration of drugs and biologicals; and
 - (g) Procedures for compliance with KRS 218A.175(4).
- (5) Referral. If an individual seeks or is in need of care and treatment beyond the scope of services offered by the facility, the facility:
- (a) Shall immediately advise the individual that he or she should seek services elsewhere; and
 - (b) May make a referral on behalf of the individual.
 - (6) Personnel.
- (a) Prescribers. Each prescriber employed or contracted by a facility shall be board certified and have a full, active, and unencumbered license to practice in the commonwealth issued under KRS Chapter 311 or 314.
 - (b) Medical director. The facility's medical director shall:
- 1. Be responsible for complying with all requirements related to the licensure and operation of the facility;
- 2. Be physically present practicing medicine in the facility for at least fifty (50) percent of the time that patients are present in the facility;
- 3. Be board certified and have a full, active, and unencumbered license to practice medicine in the commonwealth issued under KRS Chapter 311; and
- 4. Not be permitted to serve in a dual role as the medical director of both the parent facility and a satellite facility.
- (c) Medical director's qualifications. The facility's medical director shall meet one (1) of the requirements established in KRS 218A.175(3)(a) through (e).
- (d) Within ten (10) calendar days after termination of the medical director, the facility shall notify the cabinet of the identity of the individual designated as medical director, including the identity of any interim medical director, until a permanent director is secured for the facility.
- (e) The facility's medical director shall sign and submit the Pain Management Facility Data Reporting Form to the cabinet within thirty (30) calendar days of the quarter ending March 31, June 30, September 30, and December 31 of each year. The medical director shall document the following on the Pain Management Facility Data Reporting Form:
- 1. The number of new and repeat patients seen and treated at the facility who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain;
 - 2. The number of patients discharged due to drug abuse;
 - 3. The number of patients discharged due to drug diversion; and
- 4. The number of patients treated at the facility whose domicile is located somewhere other than in Kentucky. A patient's domicile shall be the patient's fixed or permanent home to which he or she intends to return even though he or she may temporarily reside elsewhere.
- (f) The medical director shall, within ten (10) days after the facility hires a prescriber of controlled substances or ten (10) days after termination of a prescriber of controlled substances, notify the cabinet in writing and report the name of the prescriber.
- (7) Staffing. At least one (1) physician and one (1) practical nurse, licensed practical nurse, or registered nurse shall be on duty in the facility during all hours the facility is operational.
- (8) Job descriptions. There shall be a written job description for each position which shall be reviewed and revised as necessary.
- (9) Personnel records. Current personnel records shall be maintained for each employee and include the following:

- (a) Name, address, and social security number;
- (b) Evidence of current certification or licensure of personnel;
- (c) Records of training and experience;
- (d) Records of each performance evaluation; and
- (e) Annual verification of certification or licensure.
- (10) In-service training.
- (a) All personnel shall participate in orientation and annual in-service training programs relating to their respective job activities.
- (b) All licensed prescribers in a facility shall comply with the professional standards established by their respective licensing boards for the completion of continuing professional education. Each licensed physician who prescribes or dispenses a controlled substance to a patient in the facility as part of his or her employment agreement with the facility shall successfully complete a minimum of ten (10) hours of Category I continuing medical education in pain management during each registration period throughout his or her employment agreement with the facility.
 - (11) Quality assurance program.
 - (a) Each facility shall have an ongoing quality assurance program that:
 - 1. Monitors and evaluates the quality and appropriateness of patient care;
 - 2. Evaluates methods to improve patient care;
 - 3. Identifies and corrects deficiencies within the facility;
- 4. Alerts the designated physician or prescribing practitioner to identify and resolve recurring problems; and
- 5. Provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public.
- (b) The medical director shall establish a quality assurance program that includes the following components:
- 1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients;
 - 2. The identification of trends or patterns of incidents;
- 3. The development and implementation of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients; and
- 4. The documentation of these functions and periodic review no less than quarterly of this information by the designated physician or prescribing practitioner.
- (12) Medical records. Each facility shall maintain accurate, readily accessible, and complete medical records that conform to the professional standards established by the respective licensing board for prescribers of controlled substances in the facility.
 - (13) Professional standards for prescribing and dispensing controlled substances.
- (a) Each licensed prescriber in a facility shall comply with the professional standards relating to the prescribing and dispensing of controlled substances established by the respective professional licensing board.
- (b) A representative from the Office of Inspector General shall review facility records, including the facility's patient records, to verify facility compliance with administrative regulations promulgated by professional licensing boards pursuant to KRS 218A.205 which establish standards for licensees authorized to prescribe or dispense controlled substances.
- (14) Kentucky Health Information Exchange (KHIE). Each facility shall participate in KHIE pursuant to the requirements of 900 KAR 9:010.

Section 8. Equipment. Equipment used for direct patient care by a facility shall comply with the requirements established in this section.

- (1) The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative and properly calibrated.
- (2) All personnel engaged in the operation of diagnostic equipment shall have adequate training and be currently licensed, registered, or certified in accordance with applicable state statutes and administrative regulations.
- (3) A written plan shall be developed and maintained to provide for training of personnel in the safe and proper usage of the equipment.
- Section 9. Physical Environment. (1) Accessibility. The facility shall meet requirements for making buildings and facilities accessible to and usable by the physically handicapped pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.
- (2) Fire safety. A new license to operate a satellite facility or a new license to operate a facility upon approval of a change of location shall not be issued before the facility obtains approval from the State Fire Marshal's office for the satellite facility or new location.
 - (3) Physical location and overall environment.
 - (a) The facility shall:
- 1. Comply with building codes, ordinances, and administrative regulations which are enforced by city, county, or state jurisdictions;
- 2. Display a sign that can be viewed by the public that contains the facility name, hours of operation, and a street address;
- 3. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four (24) hours per day;
 - 4. Have a reception and waiting area;
 - 5. Provide a restroom;
- 6. Have an administrative area, including room for storage of medical records, supplies, and equipment;
 - 7. Have private patient examination rooms;
 - 8. Have treatment rooms, if treatment is being provided to the patients; and
- 9. Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the facility's medical director and the names of all physicians and prescribers practicing in the facility.
- (b) The condition of the physical location and the overall environment shall be maintained so that the safety and well-being of patients, personnel, and visitors are assured.
 - (4) Housekeeping and maintenance services.
 - (a) The facility shall maintain a clean and safe facility free of unpleasant odors.
- (b) Odors shall be eliminated at their source by prompt and thorough cleaning of commodes, urinals, bedpans, and other sources.
 - (c)1. The facility shall provide a hand washing facility in each exam room with:
 - a. Hot and cold water and blade type operating handles;
 - b. Knee or foot controls; or
 - c. Motion activated technology.
- 2. A soap dispenser, disposable towels or electronic hand dryers, and a waste receptacle shall be provided at each hand washing sink.
 - (d) The premises shall be well kept and in good repair. Requirements shall include:
- 1. The facility shall ensure that the grounds are well kept and the exterior of the building, including the sidewalks, steps, porches, ramps, and fences are in good repair;
- 2. The interior of the building including walls, ceilings, floors, windows, window coverings, doors, plumbing, and electrical fixtures shall be in good repair. Windows and doors which can be opened for ventilation shall be screened;

- 3. Garbage and trash shall be stored in areas separate from those used for the preparation and storage of food and shall be removed from the premises regularly. Containers shall be cleaned regularly; and
- 4. A pest control program shall be in operation in the facility. Pest control services shall be provided by maintenance personnel of the facility or by contract with a pest control company. The compounds shall be stored under lock.
- (5) The facility shall develop written infection control policies that are consistent with Centers for Disease Control guidelines and include:
- (a) Prevention of disease transmission to and from patients, visitors, and employees, including:
 - 1. Universal blood and body fluid precautions;
 - 2. Precautions against airborne transmittal of infections;
 - 3. Work restrictions for employees with infectious diseases; and
- 4. Cleaning, disinfection, and sterilization methods used for equipment and the environment; and
- (b) Annual in-service education programs on the cause, effect, transmission, prevention, and elimination of infections.
 - (6) Hazardous cleaning solutions, compounds, and substances shall be:
 - (a) Labeled;
 - (b) Stored in closed metal containers;
 - (c) Kept separate from other cleaning materials; and
 - (d) Kept in a locked storage area apart from the exam room.
 - (7) The facility shall be kept free from insects and rodents, and their nesting places.
 - (8) Garbage and trash:
 - (a) Shall be removed from the premises regularly; and
 - (b) Containers shall be cleaned daily.
- (9) A facility shall establish and maintain a written policy for the handling and disposal of wastes, including any infectious, pathological, or contaminated wastes, which shall include the requirements established in this subsection.
- (a) Sharp wastes shall be segregated from other wastes and placed in puncture-resistant containers immediately after use.
- (b) A needle or other contaminated sharp shall not be recapped, purposely bent, broken, or otherwise manipulated by hand as a means of disposal, except as permitted by the Centers for Disease Control and the Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii).
 - (c) A sharp waste container shall be incinerated on or off-site or rendered nonhazardous.
- (d) Any nondisposable sharps shall be placed in a hard walled container for transport to a processing area for decontamination.
 - (10)(a) Disposable waste shall be:
 - 1. Placed in a suitable bag or closed container so as to prevent leakage or spillage; and
- 2. Handled, stored, and disposed of in such a way as to minimize direct exposure of personnel or patients to waste materials.
- (b) The facility shall establish specific written policies regarding handling and disposal of waste material.

Section 10. Inspections. (1) The cabinet shall conduct unannounced inspections of the pain management facility no less than annually, including a review of the patient records, to ensure that the facility complies with the provisions of this administrative regulation and KRS 218A.175.

- (2) A representative from the Office of Inspector General shall have access to the facility and the facility's records pursuant to KRS 216B.042.
 - (3) Violations.
- (a) The Office of Inspector General shall notify the pain management facility in writing of a regulatory violation identified during an inspection.
- (b) The facility shall submit to the Office of Inspector General, within ten (10) days of the notice, a written plan for the correction of the regulatory violation.
- 1. The plan shall be signed by the facility's administrator, the licensee, or the medical director and shall specify:
 - a. The date by which the violation shall be corrected;
 - b. The specific measures utilized to correct the violation; and
 - c. The specific measures utilized to ensure the violation will not recur.
- 2. The Office of Inspector General shall review the plan and notify the facility of the decision to:
 - a. Accept the plan;
 - b. Not accept the plan; or
- c. Deny, suspend, or revoke the license for a substantial regulatory violation in accordance with KRS 216B.105(2).
 - 3. The notice specified in subparagraph 2.b. of this paragraph shall:
 - a. State the specific reasons the plan is unacceptable; and
 - b. Require an amended plan of correction within ten (10) days of receipt of the notice.
- 4. The Office of Inspector General shall review the amended plan of correction and notify the facility in writing of the decision to:
 - a. Accept the plan;
- b. Deny, suspend, or revoke the license for a substantial regulatory violation in accordance with KRS 216B.105(2); or
 - c. Require the facility to submit an acceptable plan of correction.
- 5. A facility that fails to submit an acceptable amended plan of correction shall be notified that the license shall be denied, suspended, or revoked in accordance with KRS 216B.105(2).
 - (4) Complaints. An unannounced inspection shall be conducted:
 - (a) In response to a credible, relevant complaint or allegation; and
 - (b) According to procedures established in this section.

Section 11. Denial and Revocation. (1) The cabinet shall deny an Application for License to Operate a Pain Management Facility at the time of annual renewal or the addition of a satellite facility if:

- (a) The facility fails to comply with Section 4(2) and (3), or 7(6) of this administrative regulation:
- (b) Any person with ownership interest in the facility has had previous ownership interest in a health care facility which had its license revoked or voluntarily relinquished its license as the result of an investigation or pending disciplinary action;
- (c) An administrative sanction or criminal conviction relating to controlled substances has been imposed on the facility or any person employed by the facility for an act or omission done within the scope of the facility's license or the person's employment; or
- (d) The facility fails to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by Section 10(3) of this administrative regulation.
- (2) If during inspection of the pain management facility the cabinet has probable cause to believe that a physician or other prescriber practicing at the facility may be engaged in the im-

proper, inappropriate, or illegal prescribing or dispensing of a controlled substance, the cabinet shall:

- (a) Refer the physician or other prescriber practicing at the pain management facility to the appropriate professional licensing board and appropriate law enforcement agency; and
- (b) Suspend a facility's license pending resolution of any investigation into the matter by a licensing board or law enforcement agency, and resolution of the appeals process if applicable.
 - (3) The cabinet shall revoke a license if it finds that:
- (a) In accordance with KRS 216B.105(2), there has been a substantial failure by the facility, or its satellite facility, to comply with the provisions of this administrative regulation;
- (b) An administrative sanction or criminal conviction relating to controlled substances is imposed on the facility or any person employed by the facility for an act or omission done within the scope of the facility's license or the person's employment;
- (c) A change of ownership has occurred, except for a transfer of whole or partial ownership as permitted by KRS 218A.175(2)(b);
- (d) The facility fails to accept private health insurance as one (1) of the facility's allowable forms of payment for goods or services provided, or the facility fails to accept payment for services rendered or goods provided only from the patient or the patient's insurer, guarantor, spouse, parent, guardian, or legal custodian;
- (e) The facility fails to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by Section 10(3) of this administrative regulation; or
- (f) The facility fails to comply with Section 4(2) and (3), 7(6)(a), (b), or (c), or 7(7) of this administrative regulation.
- (4) The denial or revocation of a facility's license shall be mailed to the applicant or licensee, by certified mail, return receipt requested, or by personal service. Notice of the denial or revocation shall set forth the particular reasons for the action.
- (5) The denial or revocation shall become final and conclusive thirty (30) days after notice is given, unless the applicant or licensee, within the thirty (30) day period, files a request in writing for a hearing with the cabinet.
 - (6) Emergency action to suspend a license.
- (a) The cabinet shall take emergency action to suspend a pain management facility's license if the cabinet has probable cause to believe that:
- 1. The continued operation of the facility would constitute a danger to the health, welfare, or safety of the facility's patients or of the general public; or
- 2. A physician or other prescriber practicing at the facility may be engaged in the improper, inappropriate, or illegal prescribing or dispensing of a controlled substance.
- (b)1. The pain management facility shall cease operating immediately on the date the facility is served with the notice of emergency suspension.
 - 2. Notice of the emergency suspension shall set forth the particular reasons for the action.
- (c) If the cabinet issues an emergency suspension of the facility's license pursuant to paragraph (a)2 of this subsection, the cabinet shall refer the physician or other prescriber practicing at the pain management facility to the appropriate professional licensing board and appropriate law enforcement agency.
- (7) Notice of an emergency suspension shall be served on the facility by certified mail, return receipt requested, or by personal service.
- (8)(a) Any facility required to comply with an emergency suspension issued under subsection (6) of this section may submit a written request for an emergency hearing within five (5) calendar days of receipt of the notice to determine the propriety of the suspension.

- (b) The cabinet shall conduct an emergency hearing within ten (10) working days of the request for hearing.
- (c) Within five (5) working days of completion of the hearing, the cabinet's hearing officer shall render a written decision affirming, modifying, or revoking the emergency suspension.
- (d) The emergency suspension shall be affirmed if there is substantial evidence of an immediate danger to the public health, safety, or welfare.
- (9) The decision rendered under subsection (8) of this section shall be a final order of the agency on the matter, and any party aggrieved by the decision may appeal to circuit court.
- (10) If the cabinet issues an emergency suspension, the cabinet shall take action to revoke the facility's license pursuant to subsection (3) of this section if:
- (a) The facility fails to submit a written request for an emergency hearing within five (5) calendar days of receipt of notice of the emergency suspension;
- (b) The decision rendered under subsection (8) of this section affirms that there is substantial evidence of an immediate danger to the public health, safety, or welfare; or
- (c) Referral to a professional licensing board and law enforcement agency in accordance with subsection (6)(c) of this section results in an administrative sanction or criminal conviction relating to controlled substances against a physician or prescribing practitioner employed by, or under contract with, the facility.
 - (11) Pursuant to KRS 216B.050, the cabinet may compel obedience to its lawful orders.

Section 12. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) OIG 20:240, "Application for License to Operate a Pain Management Facility", June 2015 edition; and
 - (b) OIG 20:240-1, "Pain Management Facility Data Reporting Form", June 2012 edition.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (39 Ky.R. 684; 1212; 1409; 2027; eff. 3-4-2013; TAm. 5-28-2013; 42 Ky.R. 553; 1202; eff. 11-6-2015.)